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23117 7590 06/25/2009

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/25/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,340

01/11/2006

Stephen James Brocchini

37-88

9022

TITLE OF INVENTION: CONJUGATED BIOLOGICAL MOLECULES AND THEIR PREPARATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	09/25/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23117 7590 06/25/2009

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,340 01/11/2006 Stephen James Brocchini 37-88 9022

TITLE OF INVENTION: CONJUGATED BIOLOGICAL MOLECULES AND THEIR PREPARATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 09/25/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
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BRADLEY, CHRISTINA 1654 514-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,340	01/11/2006	Stephen James Brocchini	37-88	9022
23117	7590	06/25/2009	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			BRADLEY, CHRISTINA	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 06/25/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 260 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 260 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/564,340	BROCCHINI ET AL.	
	Examiner	Art Unit	
	CHRISTINA BRADLEY	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 03/24/2009.
2. ☒ The allowed claim(s) is/are 41-48.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>03/24/2009</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|--|---|

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

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EXAMINER'S AMENDMENT

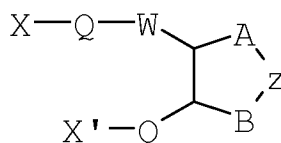
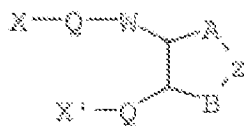
1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gary Tonigawa on 6/22/2009.

The application has been amended as follows:

Claims 1-40 (canceled)

41. (new) A protein-polymer conjugate of formula I



wherein X is a homo- or co-polymer selected from the group consisting of polyalkylene glycols, polyvinylpyrrolidones, polyacrylates, polymethacrylates, polyoxazolines, polyvinylalcohols, polyacrylamides, polymethacrylamides, HPMA copolymers, polyesters, polyacetals, poly(ortho ester)s, polycarbonates, poly(imino carbonate)s, polyamides, copolymers of divinylether-maleic anhydride and styrene-maleic anhydride, polysaccharides, and polyglutamic acids;

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Q is a linking group selected from the group consisting of a direct bond, alkylenes, optionally-substituted aryls, and optionally-substituted heteroaryls, wherein the alkylene, aryl, or heteroaryl may be terminated or interrupted by one or more oxygen atoms, sulphur atoms, keto groups, -O-CO- groups, -CO-O- groups, or -NR groups in which R is an alkyl or aryl group;

W is selected from the group consisting of a keto group, an ester group, a sulphone group, a reduced keto group, a reduced ester group, and a reduced sulphone group;

X'-Q is hydrogen;

A is a C₁₋₅ alkylene or alkenylene chain;

B is a bond or a C₁₋₄ alkylene or alkenylene chain; and

Z is a single protein linked to A and B via two thiol groups generated by reduction of a disulfide bridge in the protein.

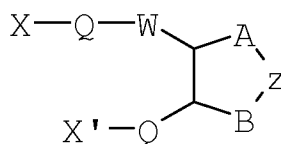
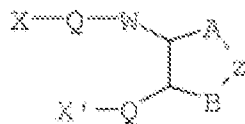
42. (new) The protein-polymer conjugate of claim 41, wherein X is a polyethylene glycol.

43. (new) A pharmaceutical composition comprising the protein-polymer conjugate of claim 41, together with a pharmaceutically acceptable carrier.

44. (new) A pharmaceutical composition comprising the protein-polymer conjugate of claim 42, together with a pharmaceutically acceptable carrier.

45. (new) A process for preparing a protein-polymer conjugate of formula I

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wherein X is a homo- or co-polymer selected from the group consisting of polyalkylene glycols, polyvinylpyrrolidones, polyacrylates, polymethacrylates, polyoxazolines, polyvinylalcohols, polyacrylamides, polymethacrylamides, HPMA copolymers, polyesters, polyacetals, poly(ortho ester)s, polycarbonates, poly(imino carbonate)s, polyamides, copolymers of divinylether-maleic anhydride and styrene-maleic anhydride, polysaccharides, and polyglutamic acids;

Q is a linking group selected from the group consisting of a direct bond, alkylenes, optionally-substituted aryls, and optionally-substituted heteroaryls, wherein the alkylene, aryl, or heteroaryl may be terminated or interrupted by one or more oxygen atoms, sulphur atoms, keto groups, -O-CO- groups, -CO-O- groups, or -NR groups in which R is an alkyl or aryl group;

W is selected from the group consisting of a keto group, an ester group, a sulphone group, a reduced keto group, a reduced ester group, and a reduced sulphone group;

X'-Q is hydrogen;

A is a C₁₋₅ alkylene or alkenylene chain;

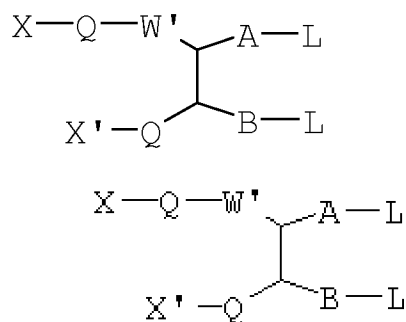
B is a bond or a C₁₋₄ alkylene or alkenylene chain; and

Z is a single protein linked to A and B via two thiol groups generated by reduction of a disulfide bridge in the protein;

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wherein the process comprises:

- (a) reducing a disulfide bridge in the protein; and
- (b) reacting the reduced protein with a compound of formula II



wherein X, Q, A, B and X'-Q are defined as above;

W' is an electron-withdrawing moiety selected from the group consisting of a keto group, an ester group, and a sulphone group; and

L is independently selected from the group consisting of -SR, -SO₂R, -OSO₂R, -N⁺R₃, -N⁺HR₂, -N⁺H₂R, halogen, and -OØ, wherein R is an alkyl or aryl group and Ø is a substituted aryl group containing at least one electron-withdrawing group.

46. (new) The process of claim 53, wherein X is a polyethylene glycol.

47. (new) The process of claim 53 further comprising reducing W' to produce a protein-polymer conjugate of formula I in which W is selected from the group consisting of a reduced keto group, a reduced ester group, and a reduced sulphone group.

48. (new) The process of claim 47, wherein X is a polyethylene glycol.

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2. Support for the newly added claims 41-48 is as follows:

- formula I is presented on pages 10 and 11 and in examples 1-7 of the original specification;
- the definition of X is found in original claim 2;
- the definition of Q is found in original claim 4;
- the definition of W is found in original claim 5 and on page 15, line 15 through page 16, line 5 of the original specification;
- the definition of z is found in original claims 8 and 9 and in examples 4-7 of the original specification;
- the definition of A and B is found in original claim 1; and
- the definition of X'-Q is found on page 22 and in examples 1-7 of the original specification.

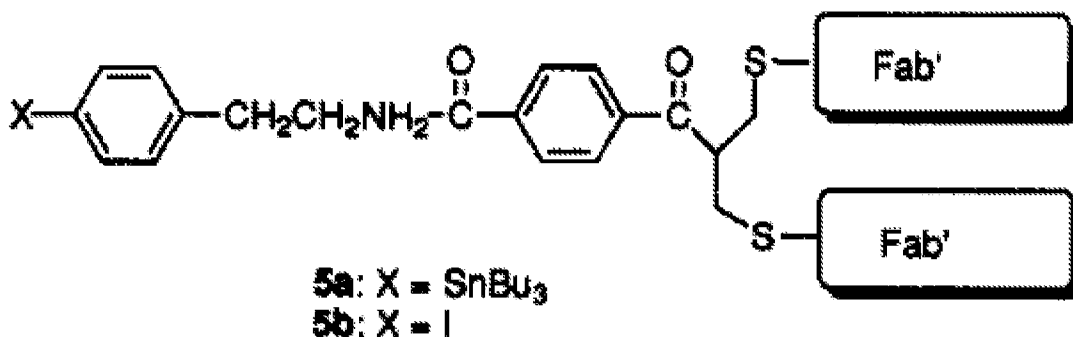
3. The following is an examiner's statement of reasons for allowance:

4. Newly added claims 41-46 overcome the issues raised under 35 U.S.C. 112, first and second paragraphs, in the previous Office action.

5. Applicant's arguments filed 03/24/2009 with respect the rejection under 35 U.S.C. 101 are persuasive.

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6. The closest prior art of Wilbur *et al.* (*Bioconj. Chem.*, **1994**, 5, 220). Wilbur *et al.* teach the site-specific cross-linking of two Fab' fragments with a trifunctional reagent via free sulfhydryls generated by the reduction of the bridging disulfides in the hinge region.



The prior art of Wilbur *et al.* differs from the instant claims in two ways: 1) the independent Fab' fragments taught by Wilbur do not meet the requirements for variable z recited in the claims as amended above; and 2) the crosslinker taught by Wilbur *et al.* does not include a polymer that meets the requirements for variable X recited in the claims as amended above.

7. With respect to the difference between intermolecular crosslinking taught by Wilbur *et al.* and intramolecular crosslinking claimed in the instant application, it would not have been obvious to apply the method of Wilbur *et al.* to a single protein in light of the unpredictability in the art associated with disruption of a disulfide bond on protein stability. The declaration under 37 C.F.R. § 1.132 filed on 03/24/2009 from Andrew George establishes the level of unpredictability in the relevant art. Dr. George states in paragraph 3 of the declaration: "I remain surprised that [that] you can replace the disulfide bond in interferon with a cross linking agent that added PEG onto the molecule - not because the chemistry would be difficult, but because I assumed that disrupting the disulfide bonds in this way would alter the properties of the

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molecule. The fact that disrupting disulfide bonds alters the properties, and particularly the biological properties, of the protein, is extremely well known, and prior to speaking with Prof. Shaunak, I would not have thought that such an approach to PEGylation was worth trying. I would have expected the resultant PEGylated protein to lack the desired biological activity.” In addition, *Analytical Chemistry for Technicians* on page 472, provided by Applicant in the response filed 03/24/2009, states “The four R group interactions are 1) hydrophobic interactions, 2) ionic (charge) attractions, 3) hydrogen bonding, and 4) disulfide bonds between cysteine residues (amino acids in a chain). Since disulfide bonds are the only covalent linkages, their presence is deemed crucial for protein stability.” Applicant summarizes the teaching of this reference on page 15 of the response filed 03/23/2009 as indicating that “the skilled person believed that a protein’s stability would be destroyed by breaking a disulfide bond therein.” In addition, the section entitled “The Role of Disulfide Bridges” in *Organic Sulfur Chemistry: Biochemical Aspects* on page 147, also provided by Applicant in the response 03/23/2009, states “When all the disulfide bridges in a protein are reduced, both the structure and function are generally lost completely.” In light of the level of skill in the art described in the response filed 03/24/2009, there would not have been a reasonable expectation of success for applying the method of Wilbur *et al.* to a single protein.

8. With respect to the difference between the reagent of Wilbur *et al.* and the instantly claimed formula I which requires a polymer, it would not have been obvious to modify the reagent of Wilbur *et al.* with a polymer and react it with a reduced disulfide bond of a single protein. Although the presence of a polymer on the trifunctional reagent is suggested by Wilbur *et al.* (Figure 1), it is not reduced to practice and Wilbur *et al.* states that incorporation of the

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polymer would require “many additional studies” (p. 234). The level of unpredictability in the art as evidenced by the declaration filed under 37 CFR § 1.132 discussed above suggests that there would not have been a reasonable expectation of success for this modification.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday-Thursday, 8:30 A.M. to 4:30 P.M.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb